REMARKS

Claims 1-25 are now pending in the subject application, with claims 21-24 being withdrawn from consideration.

I. Rejection of claims 1-19 and 25 under 35 U.S.C. § 103(a)

Claims 1-19 and 25 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over EP 0945134 to Bock et al. ("Bock (EP)") in view of U.S. Patent Application No. 2004/0204413 to Faour et al. ("Faour" for the reasons set forth in the office action. In particular, the Examiner states that "Bock is directed to oral meloxicam compositions. A granule is disclosed in Example 7. The meloxicam granules comprise meloxicam, sodium citrate, lactose (carrier) (see instant claims 1 and 13-16), polyvinylpyrrolidone (povidone; a binder) (see instant claims 1, 3 and 4)." The Examiner further states that "the meloxicam may be a sodium or meglumine salt (see claim 1; see instant claims 1 and 2). The ratio between meglumine and meloxicam is taught to be from 1.2:1 to 1:1.2 (see instant claims 19 and 19). The concentration of meloxicam in the granules is about 3.5% by weight (see Example 7; see instant claim 17)." The Examiner concedes that "Bock fails to teach the composition as comprising a sweetener and an optional flavourant. Moreover, Bock fails to teach 5g of their meloxicam granules as being capable of dissolving in 100 mL of demineralized water."

To overcome this deficiency in Bock, the Examiner relies on Faour and states that "[a]n exemplified COX-II inhibitor is meloxicam (see claim 1). It is taught that the granular formulations are to comprise a flavorant such as apple and vanilla (see [0087]." The Examiner further states that "Bock and the instant composition are essentially identical except for lacking of the sweetener and optional flavorant, otherwise the compositions are identical." The Examiner "acknowledge[s] that Bock does not teach 5 grams of their granules as possessing the ability to dissolve in 100 mL of water." Nevertheless, the Examiner states that "because the compositions are essentially identical, except for the sweetener, one would expect both to have similar pharmacological and physical properties." The Examiner further states that "absent any secondary evidence, … the granules of Bock possess similar dissolution properties as that instantly claimed." Applicants traverse.

As noted above, claim 1 of the subject application recites "water soluble meloxicam granules comprising: (a) meloxicam; (b) a salt forming agent which forms the meglumine, sodium, potassium, or ammonium salt of meloxicam; (c) a binder; (d) a sugar or sweetener; and (e) a carrier, and optionally a flavoring agent and optionally other excipients." Applicants submit that neither Bock (EP) nor Faour, either alone or in combination teaches or even suggests water soluble meloxicam granules as recited in the claims of the subject application.

Applicants believe that U.S. Patent No. 6,869,948 to Bock et al. ("Bock (US)") is an English language equivalent to Bock (EP). As discussed in the Amendment filed on October 17, 2008, Bock (US) relates to a rapidly decomposing tablet containing *inter alia* meloxicam in the form of a salt with an inorganic base (see Abstract of Bock (US)). Applicants also noted in the Amendment filed on October 17, 2008, that "even if the granulated powders described in Bock (US) 'breakdown' or 'decompose,' there is no teaching or suggestion that such granules would be water soluble as recited in the claims of the subject application."

Submitted concurrently herewith is a Declaration by Dr. Martin Folger dated May 5, 2009 ("the Folger Declaration") which discusses Bock. The Folger Declarations states in Paragraph 14 that "the data depicted in Figure 4 [of Bock] refers to the plasma concentration, which is indicative of the amount of dissolved meloxicam. However, the plasma concentration data depicted in Figure 4 provides no indication that the all of the components of the granule dissolved, including excipients." The Folger Declaration further states in Paragraph 15 that "the granulated capsule composition described by Bock in Example 7 contains cross-linked polyvinylpyrrolidone, silicon dioxide and microcrystalline cellulose. Each of these ingredients is insoluble in water including water based compositions encountered *in vivo*." The Folger Declaration further states that "including a sweetener or sugar into the granulated composition of Bock would have little effect on the solubility of the cross-linked polyvinylpyrrolidone, silicon dioxide and microcrystalline cellulose."

In summary, nothing in Bock suggests a granulated composition that would be completely water-soluble. On the contrary, as explained in the Folger Declaration, the granulated composition of Bock contains water-insoluble components such as cross-linked

polyvinylpyrrolidone, silicon dioxide and microcrystalline cellulose. And as further explained in the Folger Declaration, none of these water-insoluble components would be expected to become water soluble when combined with a sweetener or sugar as taught in Faour.

"A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02.VI (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983)).

As discussed above and explained in the Folger Declaration, the granulated composition described in Bock cannot be completely water-soluble, because Bock's granules contain water-insoluble components such as cross-linked polyvinylpyrrolidone, silicon dioxide and microcrystalline cellulose. As further explained in the Folger Declaration, modifying Bock's granules to include a sweetener or sugar would have little, if any effect, on the solubility of these water-insoluble components. Moreover, nothing in Faour suggests modifying Bock's granules to remove these water-insoluble components and/or replace them with water-soluble components. Because the granules described by Bock are not completely water-soluble, and because nothing in Faour teaches or suggests modifying Bock's water-insoluble granules, the combination of Bock and Faour would lead away from the water-soluble granules recited in claims 1-19 and 25 of the subject application. Therefore, claims 1-19 and 25 of the subject application are not obvious over Bock in view of Faour.

In view of the above, Applicants respectfully submit that claims 1-19 and 25 are not obvious over Bock in view of Faour and request that the rejection of claims 1-19 and 25 under 35 U.S.C. § 103(a) be withdrawn.

II. Rejection of claim 20 under 35 U.S.C. § 103(a)

The Examiner rejected claim 20 under 35 U.S.C. § 103(a) as allegedly being obvious over the Bock, in view of Faour, and further in view of Parikh, The Handbook of Pharmaceutical Granulation Technology, 1st Ed., 1997, Marcel Dekker, pp. 60-72 ("Parikh"), for the reasons set forth in the Office Action. The Examiner states that "Bock fails to teach a composition which comprises meloxicam, meglumine, hydroxypropylmethylcellulose, povidone, and glucose monohydrate (dextrose." The

Examiner further states that "Faour teaches that the carrier for their granular composition may be lactose or dextrose. Faour also teaches that the binder for the granular composition can be povidone (see [0076] and [0077])." The Examiner still further states that Parikh is drawn to a variety of binders to be used in granulating granules. It is taught that binders are provided to provide a cohesive force to the granules. Binders include natural and synthetic binders such as povidone and hydroxypropyl methylcellulose (HPMC)." The Examiner contends that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bock, Faour, and Parikh with a reasonable expectation of success in arriving at a water soluble granule composition comprising meloxicam, meglumine, HPMC, povidone and glucose monohydrate."

Applicants traverse this rejection. As discussed above and explained in the Folger Declaration, the combination of Bock and Faour would lead away from a water-soluble granular composition as recited in claim 20. With regard to Parikh, the Folger Declaration states at Paragraph 19

> Nothing in Parikh suggests that these water-insoluble components should be replaced by water-soluble components. Thus, even if the granulated capsule of Bock was modified to include povidone and HPMC, nothing in Parikh suggests replacing the other water-insoluble components used in Bock's granules, i.e., silicon dioxide and microcrystalline cellulose.

In summary, Bock in view of Faour would not lead to a water-soluble meloxicam granule for the reasons set forth in Section I above. Moreover, this deficiency of Bock in view Faour is not overcome further in view of Parikh for the reasons explained in the Folger Declaration and discussed above. Therefore, even if Parikh teaches a variety of binders to be used in granulating granules, the combination of Faour and Parikh would provide any suggestion or motivation to modify the granular composition of Bock to provide a water-soluble granule.

In view of the above, Applicants respectfully submit that claim 20 is not obvious over Bock in view of Faour, and further in view of Parikh, and request that the rejection of claim 20 under 35 U.S.C. § 103(a) be withdrawn.

III. Rejoinder of claims 21-24

As discussed above, Applicants believe that claim 1 is now allowable. Accordingly, Applicants request the rejoinder of withdrawn process claims 21-24 which depend directly or indirectly upon claim 1. ("If applicant elects a claim(s) directed to a product which is subsequently found allowable, withdrawn process claims which depend from or otherwise require all the limitations of an allowable product claim will be considered for rejoinder"(see MPEP § 824.04(b))).

CONCLUSION

Applicants respectfully request prompt consideration of the pending claims and early allowance of the application. No additional fee is believed due. However, if any additional fee is due, the Examiner is authorized to charge the fee to Applicants' Deposit Account No. 02-2955.

If a telephonic or personal interview is deemed necessary to expedite the examination of the instant application, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

/David L. Kershner/
David L. Kershner
Attorney for Applicant(s)
Reg. No. 53,112

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT. 06877
Tel.: (203) 791-5469
Fax: (203) 798-4408

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